

## REMARKS

### Claim Rejections – 35 USC §102 and §103

Claims 1-20, 28-42, 44-46 and 48-60 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,059,193 to Kuslich. Additionally, claims 21, 43 and 47 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kuslich, and claims 22-27 have been rejected as being unpatentable over Kuslich in view of U.S. Patent No. 6,371,989 to Chauvin.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

With regard to Kuslich, disclosed therein is an implant 10 including a body 12 and an expander 14. The implant body 12 is initially provided in a cylindrical configuration (Figure 3) which is transitioned to a spherical configuration (Figures 1 and 2) via the implant expander 14. As shown in Figure 3, the implant body 12 includes a tubular shell 22 having a plurality of longitudinally extending slots 24 which define a plurality of axially-extending ribs 26 that are interconnected via a pair of end rings 23. The implant expander 14 includes a tie rod 16 and an attachable end cap 18. As shown in Figure 4, the tie rod 16 includes an integrally molded end cap 32 and a tie rod post 40 provided with a plurality of barbs 44. As shown in Figures 6 and 7, the attachable end cap 18 includes a notched bore 52 having notches 54 that are complementarily sized to receive the barbs 44 of the tie rod 16. The end caps 18, 32 of the implant expander 14 abut the end rings 23 of the implant body 12. As the tie rod 16 is pulled through the notched bore 52 in the end cap 18, the end caps 18, 32 are drawn together, thereby exerting a compressive force onto the end rings 23 of the implant body 12, which in turn causes the axially-extending ribs 26 to arc outwardly to transition the implant body 12 to the spherical configuration illustrated in Figures 1 and 2.

**Independent Claim 1 and Dependent Claims 2-29**

The Applicant has amended independent claim 1 to recite an implant body including first and second axial walls spaced apart along a transverse axis and having pairs of opposite end portions that are interconnected with one another, and “an expansion member engaged with said first and second axial walls at a location intermediate said first and second pairs of opposite end portions and extending transversely between central portions of said first and second axial walls to expand said body along said transverse axis”. Support for the amendment to independent claim 1 is found, for example, in paragraphs 27, 28, 43 and 46 of the published application, and in Figures 1 and 7.

Even assuming arguendo that the axially-extending ribs 26 of the Kuslich implant comprise first and second axial walls including end portions that are transversely interconnected via the end rings 23, the implant expander 14 is not engaged with the axially-extending ribs 26 at a location intermediate the end rings 23, and also does not extend transversely between central portions of the axially-extending ribs 26 to expand the implant body 12 along a transverse axis. To the contrary, the end caps 18, 32 of the implant expander 14 abut the end rings 23 of the implant body 12, with the tie rod 16 extending axially along the ribs 26. Neither the end caps 18, 32 nor the tie rod 16 are in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Furthermore, neither the end caps 18, 32 nor the tie rod 16 extend transversely between central portions of the axially-extending ribs 26 to transversely expand the implant body 12. Indeed, as clearly illustrated in Figures 1-3 and as described above, the only portions of the implant expander 14 which engage the implant body 12 are the ends caps 18, 32 which axially abut the end rings 23 of the implant body 12. However, the end caps 18, 32 are clearly not engaged with the axially-extending ribs 26 at a location intermediate the end rings 23, and do not extend transversely between central portions of the axially-extending ribs 26 to expand the implant body. Instead, the end caps 18, 32 are drawn together to exert an axial compressive force onto the end rings 23 of the implant body 12, which in turn causes the axially-extending ribs 26 to outwardly arc to transition the implant body 12 to the spherical configuration illustrated in Figures 1 and 2.

With regard to the expandable implant recited in independent claim 1, engagement of the expansion member with the axial walls at a location intermediate the opposite end portions and

extension of the expansion member transversely between central portions of the axial walls not only serves to transversely expand the implant body, but also provides transverse support to the axial walls at a central location to resist compression loading onto the implant body by the adjacent vertebrae and to provide structural stability and rigidity to the implant body. Indeed, as set forth in paragraph 56 of the published application, “positioning of the expansion pin 24 within the center compartment 90c of the inner chamber 40 provides additional support and rigidity to the upper and lower walls 30, 32 of the fusion cage 22 to resist compression loads from the vertebral bodies  $V_U$ ,  $V_L$ , particularly near the central portion 22c of the fusion cage 22 which is otherwise devoid of internal support members.” However, the Kuslich implant fails to provide any type of transverse support to the axially-extending ribs 26 at a central location of the implant body 12, but instead relies solely on the axial compressive force exerted onto the end rings 23 of the implant body to expand the implant body and to resist vertebral loading.

For at least the reasons set forth above, the Applicant submits that the expandable implant recited in independent claim 1 is patentable over Kuslich. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1 and allowance of the same. The Applicant notes that dependent claim 11 has been amended to correct an informality. Claims 2-29 depend from independent claim 1 and are patentable for at least the reasons set forth above in support of the patentability of independent base claim 1.

### **Independent Claim 30**

The Applicant has amended independent claim 30 to recite an implant body including first and second axial walls spaced apart along a transverse axis and first and second transverse end walls extending between and interconnecting opposing end portions of said first and second axial walls, and means for expanding said first and second axial walls along said transverse axis with “said means for expanding engaging said first and second axial walls at a location intermediate said first and second transverse end walls and extending transversely between central portions of said first and second axial walls to expand said body along said transverse axis”. Support for the amendment to independent claim 30 is found, for example, in paragraphs 27, 28, 43 and 46 of the published application, and in Figures 1 and 7.

Even assuming arguendo that the axially-extending ribs 26 of the Kuslich implant comprise first and second axial walls, and that the end rings 23 comprise first and second transverse end walls extending between and interconnecting opposing end portions of the axially-extending ribs 26, the implant expander 14 does not comprise means for transversely expanding the implant body 12 which engages the axially-extending ribs 26 “at a location intermediate said first and second transverse end walls and extending transversely between central portions of said first and second axial walls” to expand the implant body 12 along a transverse axis. As indicated above with regard to independent claim 1 and as illustrated in Figures 1-3 of Kuslich, neither the end caps 18, 32 nor the tie rod 16 are in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Furthermore, neither the end caps 18, 32 nor the tie rod 16 extend transversely between central portions of the axially-extending ribs 26 to transversely expand the implant body 12. Indeed, the only portions of the implant expander 14 which engage the implant body 12 are the ends caps 18, 32 which axially abut the end rings 23 of the implant body 12. However, the end caps 18, 32 are clearly not engaged with the axially-extending ribs 26 at a location intermediate the end rings 23, and do not extend transversely between central portions of the axially-extending ribs 26 to expand the implant body.

For at least the reasons set forth above, the Applicant submits that the expandable implant recited in independent claim 30 is patentable over Kuslich. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 30 and allowance of the same.

#### **Independent Claim 31 and Dependent Claims 32-36**

The Applicant has amended independent claim 31 to recite an implant body having an implant width and an implant length and including first and second axial walls and “first and second transverse end walls extending between and interconnecting opposing end portions of said first and second axial walls, said transverse end walls defining generally flat upper and lower vertebral bearing surfaces extending across said implant width”, and an expansion member co-acting with the first and second axial walls to expand the implant body along the transverse axis such that the first and second axial walls are outwardly deformed to define a convex outer

curvature extending along the implant length. Support for the amendment to independent claim 31 is found, for example, in paragraphs 29 and 55 of the published application, dependent claim 59, and in Figures 1, 2 and 7.

Even assuming *arguendo* that the axially-extending ribs 26 of the Kuslich implant comprise first and second axial walls and that the end rings 23 comprise first and second transverse end walls extending between and interconnecting opposing end portions of the axially-extending ribs 26, the end rings 23 do not define “generally flat upper and lower vertebral bearing surfaces extending across said implant width”, as recited in independent claim 31. Instead, as illustrated in Figure 3 of Kuslich, the end rings 23 each have a disc-like circular configuration defining a circular outer surface, and clearly do not define “generally flat upper and lower vertebral bearing surfaces” extending across a width of the implant body 12.

As set forth in the subject application, the upper and lower surfaces 50, 52 of the implant body “define upper bearing surfaces 54a, 54b and lower bearing surfaces 56a, 56b adjacent the end walls 34, 36 . . . [that] contact and bear against the cortical rim/apophyseal ring region of the respective upper and lower vertebral bodies  $V_U$ ,  $V_L$  (FIGS. 6-8) to provide support and resistance to a substantial amount of the compressive forces exerted onto the fusion cage 22” and “to reduce the likelihood of subsidence into the relatively softer cancellous or spongiseum bone tissue.” (See paragraphs 29 and 55 of the published application). However, Kuslich discloses a cylindrical-shaped implant body 12 including circular end rings 23 which require that a circular opening 114 be cut into the upper and lower vertebrae 100, 110 to form a circular opening 114 for receiving the implant body 12. As indicated in paragraph 3 of the subject application, these types of cylindrical-shaped implant designs require reaming of the adjacent vertebral bodies to form a passage for receiving the implant. Additionally, “these techniques generally involve over-reaming of the posterior portion of the adjacent vertebral bodies, thereby resulting in excessive removal of load bearing vertebral bone which may lead to instability of the portion of the spinal column being treated.” The implant body recited in independent claim 31, however, is provided with first and second transverse end walls “defining generally flat upper and lower vertebral bearing surfaces extending across said implant width”. Accordingly, removal of excessive amounts of vertebral bone to accommodate circular end walls of a cylindrical-shaped implant is not required, thereby providing increased support and resistance to the compressive

forces exerted onto the implant and also reducing the likelihood of subsidence into the relatively softer cancellous or spongiseum bone tissue.

For at least the reasons set forth above, the Applicant submits that the expandable implant recited in independent claim 31 is patentable over Kuslich. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 31 and allowance of the same. The Applicant notes that dependent claim 32 has been cancelled without prejudice in view of the amendment to independent claim 31. Additionally, dependent claim 33 has been amended to recite wherein movement of the expansion member within the inner chamber “engages said expansion member with said first and second axial walls at a location intermediate said first and second transverse end walls and extending transversely between central portions of said first and second axial walls to outwardly deform said first and second axial walls along said transverse axis”. Support for the amendment to dependent claim 33 is found, for example, in paragraphs 27, 28, 43 and 46 of the published application, and in Figures 1 and 7. Claims 33-36 depend from independent claim 31 and are patentable for at least the reasons set forth above in support of the patentability of independent base claim 31.

**Independent Claim 37 and Dependent Claims 38-44**

The Applicant has amended independent claim 37 to recite an implant body including first and second axial walls spaced apart along a transverse axis and first and second transverse end walls extending between and interconnecting opposing end portions of the first and second axial walls, and “an expansion member engaged with said first and second axial walls at a location intermediate said first and second transverse end walls and extending transversely between central portions of said first and second axial walls to transition said body from an initial configuration to an expanded configuration wherein said first and second axial walls are outwardly deformed away from one another along said transverse axis”. Support for the amendment to independent claim 37 is found, for example, in paragraphs 27, 28, 43 and 46 of the published application, and in Figures 1 and 7.

Even assuming arguendo that the axially-extending ribs 26 of the Kuslich implant comprise first and second axial walls, and that the end rings 23 comprise first and second transverse end walls extending between and interconnecting opposing end portions of the

axially-extending ribs 26, no portion of the implant expander 14 is engaged with the axially-extending ribs 26 at a location intermediate the end rings 23 and extending transversely between central portions of the axially-extending ribs 26 to transition the implant body 12 to an expanded configuration wherein the axially-extending ribs 26 are outwardly deformed away from one another along a transverse axis. As indicated above with regard to independent claim 1 and as illustrated in Figures 1-3 of Kuslich, neither the end caps 18, 32 nor the tie rod 16 are in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23.

Furthermore, neither the end caps 18, 32 nor the tie rod 16 extend transversely between central portions of the axially-extending ribs 26 to outwardly deform the axially-extending ribs 26 away from one another along a transverse axis. Indeed, the only portions of the implant expander 14 which engage the implant body 12 are the end caps 18, 32 which axially abut the end rings 23 of the implant body 12. However, the end caps 18, 32 are clearly not engaged with the axially-extending ribs 26 at a location intermediate the end rings 23, and do not extend transversely between central portions of the axially-extending ribs 26 to expand the implant body 12.

For at least the reasons set forth above, the Applicant submits that the expandable implant recited in independent claim 37 is patentable over Kuslich. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 37 and allowance of the same. Claims 38-44 depend from independent claim 37 and are patentable for at least the reasons set forth above in support of the patentability of independent base claim 37.

#### **Independent Claim 45 and Dependent Claims 46-49**

The Applicant has amended independent claim 45 to recite a fusion cage including first and second axial walls spaced apart along a transverse axis and defining an inner chamber having a central portion and opposite first and second end portions, “an expansion member positioned within said central portion of said inner chamber and engaged with said first and second axial walls at a location intermediate said first and second end portions of said inner chamber and extending transversely between central portions of said first and second axial walls to expand said fusion cage along said transverse axis”, and a bone growth promoting material positioned within the first and second end portions of the inner chamber on opposite sides of the

expansion member. Support for the amendment to independent claim 45 is found, for example, in paragraphs 27, 28, 43 and 46 of the published application, and in Figures 1 and 7.

Even assuming arguendo that the axially-extending ribs 26 of the Kuslich implant comprise first and second axial walls defining an inner chamber having a central portion and opposite first and second end portions, no portion of the implant expander 14 is engaged with the axially-extending ribs 26 at a location intermediate the end rings 23 and extending transversely between central portions of the axially-extending ribs 26 to expand the implant body 12 along a transverse axis. As indicated above with regard to independent claim 1 and as illustrated in Figures 1-3 of Kuslich, neither the end caps 18, 32 nor the tie rod 16 are in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Furthermore, neither the end caps 18, 32 nor the tie rod 16 extend transversely between central portions of the axially-extending ribs 26 to transversely expand the implant body 12. Indeed, the only portions of the implant expander 14 which engage the implant body 12 are the ends caps 18, 32 which axially abut the end rings 23. However, the end caps 18, 32 are clearly not engaged with the axially-extending ribs 26 at a location intermediate the end rings 23, and do not extend transversely between central portions of the axially-extending ribs 26 to transversely expand the implant body 12.

For at least the reasons set forth above, the Applicant submits that the expandable implant recited in independent claim 45 is patentable over Kuslich. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 45 and allowance of the same. Claims 46-49 depend from independent claim 45 and are patentable for at least the reasons set forth above in support of the patentability of independent base claim 45.

#### **Independent Claim 50 and Dependent Claims 51-60**

The Applicant has amended independent claim 50 to recite a surgical method comprising the steps of providing an expandable intervertebral implant including first and second axial walls and first and second transverse end walls extending between and interconnecting opposing end portions of the first and second axial walls, inserting the intervertebral implant within an intervertebral space, “positioning an expansion member between the first and second axial walls”, and “expanding the intervertebral implant along the transverse axis by engaging the



expansion member with the first and second axial walls at a location intermediate the first and second transverse end walls with the expansion member extending transversely between mid-portions of the first and second axial walls to engage the first and second axial walls against the respective first and second vertebral bodies”. Support for the amendment to independent claim 50 is found, for example, in paragraphs 27, 28, 43 and 46 of the published application, and in Figures 1 and 7.

Even assuming *arguendo* that the axially-extending ribs 26 of the Kuslich implant comprise first and second axial walls, and that the end rings 23 comprise first and second transverse end walls extending between and interconnecting opposing end portions of the axially-extending ribs 26, no portion of the implant expander 14 is engaged with the axially-extending ribs 26 at a location intermediate the end rings 23 and extending transversely between mid-portions of the axially-extending ribs 26 to expand the implant body 12 to engage the axially-extending ribs 26 against the adjacent vertebral bodies. As indicated above with regard to independent claim 1 and as illustrated in Figures 1-3 of Kuslich, neither the end caps 18, 32 nor the tie rod 16 are in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Furthermore, neither the end caps 18, 32 nor the tie rod 16 extend transversely between central portions of the axially-extending ribs 26. Indeed, the only portions of the implant expander 14 which engage the implant body 12 are the end caps 18, 32 which axially abut the end rings 23 of the implant body 12. However, the end caps 18, 32 are clearly not engaged with the axially-extending ribs 26 at a location intermediate the end rings 23, and do not extend transversely between central portions of the axially-extending ribs 26 to expand the implant body 12.

For at least the reasons set forth above, the Applicant submits that the surgical method recited in independent claim 50 is patentable over Kuslich. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 50 and allowance of the same. The Applicant notes that dependent claim 57 has been amended in view of the amendment to independent claim 50. Claims 51-60 depend from independent claim 50 and are patentable for at least the reasons set forth above in support of the patentability of independent base claim 50.

## CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 1-31 and 33-60. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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